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### **Reason for Non-entry of Claim Amendments**

The Applicant has amended claim 21 and 24, and inserted the following new limitations;

- The probiotic activity halting agent renders the microorganism non-viable;
- At least once living dihydrolipoic acid-producing probiotic organism;

which raise new issues that would require further consideration and/or search, including issues of new matter.

These limitations were not presented before the Final Office Action was issued. New limitations require new considerations and the possibility of a new search would not be proper since the action was already made final and prosecution is closed. Please See M.P.E.P. § 714.12 and 714.13 for further information.

Furthermore all arguments presented After Final are drawn to these amendments and are not considered at this time since they will not be entered.

It should be kept in mind that applicant cannot, as a matter of right, amend any finally rejected claims, add new claims after a final rejection (see 37 CFR 1.116) or reinstate previously canceled claims.

Except where an amendment merely cancels claims, adopts examiner suggestions, removes issues for appeal, or in some other way requires only a cursory review by the examiner, compliance with the requirement of a showing under 37 CFR 1.116(b)(3) is expected in all amendments after final rejection, i.e., " An amendment touching the merits of the application or patent under reexamination may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and was not earlier presented."

### **New Matter**

The amendment to claim 21 that the "probiotic activity halting agent...render[s] the microorganisms non-viable" does not have explicit support in the specification. The actual word

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"non-viable" is not found in the specification. Also claim 24 appears to introduce new matter by limiting that the "dihydrolipoic acid-producing probiotic organism" is "once living". References in the specification to vitality such as "once living" only refer to the DHLA source and not the probiotic microorganisms as amended in claim 24. In the claims the source of the DHLA and the probiotic are separate components in the composition. Therefore these amendments appear to introduce new matter not previously submitted in the disclosure.

### **Response For Reconsideration of the Term "halt"**

The Applicant argues that the term "halt" is interpreted too broadly in view of the specification and that one of ordinary skill in the art would understand that "halt" means to "a complete and permanent stop"( Applicant's Reply, . pg 8, Bottom). The Applicant has submitted several dictionary references to support their assertion. However these were not persuasive.

Webster's New Encyclopedic Dictionary and Merriam Webster's Collegiate dictionary definitions refer to marching or journeying and do not imply that the word has a permanent meaning. Indeed the most comprehensive definition provided by the Applicant in the Random House Webster's Unabridged Dictionary provides that the term "halt" can either be permanent or temporary.

The Applicant then asserts in their response as well as with a 1.132 Declaration by Dr. Dinesh-Kumar Patel that in biochemistry the term "halt" when applied to probiotics means "a complete and permanent cessation of probiotic activity" (Declaration, paragraph 9). However this is not convincing in light of the guidance provided by MPEP 2111.01 IV which states:

An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). [I]nventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and

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precision" and, if done, must "'set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change" in meaning). Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." (M.P.E.P 2111.01 IV, Citation Omitted)

Since the Applicant has not provided a clear, deliberate, and precise re-telling of the term "halt", the Examiner is bound to interpret it with its ordinary, customary meaning. Therefore the Examiner's interpretation of the term "halt" remains and the previous rejection stands.